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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,775	02/09/2004	Clifford Eugene Gammons	27455.00	9324
22465	7590	04/06/2007	EXAMINER	
PITTS AND BRITTIAN P C			BOUCHELLE, LAURA A	
P O BOX 51295			ART UNIT	PAPER NUMBER
KNOXVILLE, TN 37950-1295			3763	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/06/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,775	GAMMONS, CLIFFORD EUGENE	
	Examiner	Art Unit	
	Laura A. Bouchelle	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 January 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-13 and 15-18 is/are rejected.
- 7) Claim(s) 3,4,15,16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review.(PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 112

1. Claim 1, 8, 13 recites the limitation "distal end of the medical probe". There is insufficient antecedent basis for this limitation in the claim. It is unclear whether or not the medical probe is being claimed. The Examiner suggests changing each instance of this language to recite, "distal end of a medical probe."

Claim Objections

2. Claims 3, 4, 15, 16 are objected to because of the following informalities: Claims 3, 4 depend from cancelled claim 2. Claims 15, 16 depend from cancelled claim 14. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci et al (US 4140127) in view of Wu et al (US 4246909).
5. Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double

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thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2. Cianci inherently discloses the steps of providing a first panel 28a and a second panel 28b and folding the panels and heat sealing the panels to each other. The claim 1 limitation of folding the panels prior to securement is considered to be a product by process limitation. These claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production. See MPEP 2113.

6. Claim 1 differs from Cianci in calling for the cover to further comprise a throat. Claim 3 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe. Wu teaches a cover 10 for a medical probe having a throat 37 that has been heat sealed with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

7. Claims 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Wu in further view of Barnes et al (US 3812769). Claims 13 and 15 differ from Cianci in calling for the step of providing a throat with the specified circumference. Wu teaches a cover 10 for a medical probe having a throat 37 that has been heat sealed with a width that is less than

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one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

8. Claim 13 further differs from the teachings of Cianci in view of Wu in calling for the step of folding the first and second panels before securing the members together. Barnes teaches a method of manufacturing a two ply bag including the steps of first folding the first and second panels then sealing them together (Col. 1, line65- Col. 2, line 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Cianci to include folding the panels before securing them as taught by Barnes as a low cost and efficient way to make a two-ply member.

9. Claims 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Wu or Cianci in view of Barnes in view of Wu as applied to claims 1 and 13 above, and further in view of Poncy (US 4165000). Claim 4 differs from Cianci in view of Wu in calling for the first end of the cover to define a funnel configuration. Claim 16 differs in calling for the step of defining the funnel. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration defined by a heat sealing die to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill

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in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

10. Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Wu in view of Poncy or Cianci in view of Wu in view of Barnes in view of Poncey. Claim 5 differs from Cianci in calling for the first panel member to extend beyond the second panel. Claim 17 differs in calling for the step of defining the extended portion. Poncy teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

11. Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Wu in view of Gammons et al (US 6224543) or Cianci in view of Wu in view of Barnes in view of Gammons. Claim 6 differs from Cianci in calling for the cover to be partially inverted. Claim 18 differs from Cianci in view of Barnes in calling for the step of inverting the second end. Gammons teaches a sheath having a second end that has been inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Wu in further view of Weaver (US 5667068). Claim 7 differs from Cianci in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to be formed of an elastic material as taught by Weaver to protect the delicate probe.

13. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Poncy and further in view of Wu. Cianci discloses a catheter sheath having a first panel member 48a and a second panel member 48b defining a tubular configuration, the first panel being folded over to form a double thickness, and the second panel being folded over to form a double thickness (Col. 3, lines 30-40). See Fig. 2.

14. Claim 8 differs from Cianci in calling for the first panel member to extend beyond the second panel. Poncy teaches a cover having a first panel 24 that projects beyond the end of the second panel 22 to serve as a guide to facilitate inserting the probe into the sheath (Col. 3, lines 60-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a first panel extending beyond the second panel as taught by Poncy to facilitate insertion of the probe into the sheath.

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15. Claim 8 further differs from Cianci in view of Poncy in calling for in calling for the cover to further comprise a throat. Claim 9 differs in calling for the width of the throat to be less than one half of the circumference of the medical probe. Wu teaches a cover 10 for a medical probe having a throat 37 with a width that is less than one half of the circumference of the medical probe so that the cover cannot inadvertently slide off of the probe (Col. 3, lines 18-22, 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover of Cianci to have a throat of less than one half the circumference of the probe as taught by Wu so that the cover cannot inadvertently slide off of the probe.

16. Claim 10 differs from the teachings above in calling for the cover to have a funnel configuration. Poncy teaches a medical probe cover having a first end with a flaring or funnel configuration to facilitate the insertion of the medical probe (Col. 4, lines 18-22). See Fig. 5. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to have a first end with a funnel configuration as taught by Poncy to facilitate insertion of the probe.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Poncy in further view of Wu as applied to claim 8 above, and further in view of Gammons. Claim 11 differs from the teachings above in calling for the cover to be partially inverted. Gammons teaches a sheath having a second end that is inverted to facilitate movement of the sheath onto the tip of a medical probe (Col. 1, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be

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partially inverted as taught by Gammons to facilitate movement of the sheath onto the tip of a medical probe.

18. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cianci in view of Poncy in further view of Wu as applied to claim 8 above, and further in view of Weaver. Claim 12 differs from the teachings above in calling for the cover to be fabricated of a material having elastomeric properties. Weaver teaches a protective cover for a medical probe formed of an elastic material so that the cover can protect the delicate probe (Col. 2, lines 61-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cover above to be formed of an elastic material as taught by Weaver to protect the delicate probe.

Response to Arguments

19. Applicant's arguments filed 1/19/07 have been fully considered but they are not persuasive.

20. Applicant argues that Cianci does not teach that the double thickness maintains the cover on the probe. The teaching reference Wu teaches that a throat has sufficient rigidity to maintain the cover on a probe, were the probe sized in such a way as to be slightly larger than the diameter of the throat. Applicant is encouraged to further define the throat and add language as to how the throat and the double thickness function to maintain the cover on the probe. The examiner points

applicant to paragraph 23 of the specification for language that would further define the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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